K012591

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WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the ADVANCE® Unicondylar Knee System.

Submitted By:	Wright Medical Technology, Inc.
Date:	August 9, 2001
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs
Proprietary Name:	ADVANCE® Unicondylar Knee System
Common Name:	UNICONDYLAR KNEE SYSTEM
Classification Name and Reference:	21 CFR 888.3520 Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer – Class II 21 CFR 888.3530 Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer – Class II
Device Product Code and Panel Code:	Orthopedics/87/ HSX, HRY

DEVICE INFORMATION

A. INTENDED USE

Indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

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Unicondylar knee system is indicated for patients with unicompartmental joint disease secondary to the above indications with or without valgus, varus, or flexion deformities where all ligaments are intact.

The ADVANCE® Unicondylar Knee System components are for single use only.

The ADVANCE® Unicondylar Knee System components are for cemented use only.

B. DEVICE DESCRIPTION

The ADVANCE® Unicondylar Knee System contains anatomically shaped, medial, non-porous Co-Cr femoral components. The tibial components will consist of all-poly ultra-high molecular-weight polyethylene (UHMWPE) tibial implants.

The ADVANCE® Unicondylar Femoral component will be available in four anatomic sizes (to provide coverage of the condyle from posterior to anterior). The anatomic shape of the femoral component necessitates separate left and right configurations.

The ADVANCE® Unicondylar Tibial component will be available in four sizes (universal in shape- no lefts and rights).

The design features of ADVANCE® Unicondylar Knee System are substantially equivalent to the design features of competitive devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of ADVANCE® Unicondylar Knee System are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of ADVANCE® Unicondylar Knee System are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

WRIGHT
MEDICAL TECHNOLOGY, INC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K012591
Trade/Device Name: ADVANCE® Unicondylar Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: August 9, 2001
Received: August 10, 2001

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhauser

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012591

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MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
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ADVANCE® Unicondylar Knee System

INDICATIONS STATEMENT

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K012591

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)